UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/849,862	09/04/2007	Howard L. Levine	CL028x-US	6447

20529 7590 02/03/2017

NATH, GOLDBERG & MEYER
Joshua Goldberg
112 South West Street
Alexandria, VA 22314

EXAMINER	
CABRAL, ROBERT S	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
02/03/2017	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO@nathlaw.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte HOWARD L. LEVINE,
WILLIAM J. BOLOGNA, and DOMINIQUE DE ZEIGLER

Appeal 2014-005216
Application 11/849,862
Technology Center 1600

Before DONALD E. ADAMS, JEFFREY N. FREDMAN, and JOHN G. NEW, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

This appeal under 35 U.S.C. § 134(a) involves claims 3–7, 10, 11, 26, 27, 45, and 46 (App. Br. 7; Final Act. 2[2]). Examiner entered rejections under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a). We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

---

[1] Appellants identify the real party in interest as "Columbia Laboratories, Inc." (App. Br. 3).

[2] Examiner's January 17, 2013 Final Office Action. We note Examiner's reference to Examiner's June 27, 2012 Non-Final Office Action (Non-Final Act.) for the statement of, and rationale for, the anticipation and obviousness rejections before this Panel for review (*see* Final Act. 2).

STATEMENT OF THE CASE

Appellants disclose "a pharmaceutical composition for treating or preventing pelvic pain associated with uterine dysrhythmia, as well as to a method for treating or preventing such pain" (Spec. 1:11–13). In this regard, Appellants disclose that their

> method focus[es] in part on local, topical use of treating agents for absorption into local tissue to prevent or treat the underlying abnormal or undesireable [sic] muscle contractions that are causing the pain or discomfort rather than merely relieving or masking the resulting pain or discomfort without affecting the cause.

(*Id.* at 13–17). Claim 26 is representative and reproduced below:

> 26. A method of pre-treating or preventing pelvic pain associated with uterine dysrhythmia, comprising vaginally administering, to a patient in need thereof, a composition that includes a therapeutically effective amount of lidocaine, which normalizes abnormal uterine contractions, and a bioadhesive, water-swellable, water-insoluble, cross-linked polycarboxylic acid polymer that releases the lidocaine over an extended period of time after administration, *wherein the treatment is administered prior to anticipated onset of pelvic pain associated with uterine dysrhythmia so as to prevent pelvic pain associated with uterine dysrhythmia, wherein the pelvic pain is also associated with secondary dysmenorrhea*.

(App. Br. 22 (emphasis added).)

The claims stand rejected as follows:

Claims 3–7, 10, 11, 26, 27, 45, and 46 stand rejected under 35 U.S.C. § 102(b) as anticipated by Harrison.[3]

[3] Harrison et al., WO 98/56323 A1 (publ. Dec. 17, 1998).

Claims 3–7, 10, 11, 26, 27, 45, and 46 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Harrison and Edelstam.[4]

Anticipation:

ISSUE

Does the preponderance of evidence on this record support Examiner's finding that Harrison teaches Appellants' claimed invention?

FACTUAL FINDINGS (FF)

FF 1. Appellants disclose:

> Dysmenorrhea is associated with pain typically related to the menstrual cycle and can be primary or secondary. . . . [P]rimary dysmenorrhea . . . pain is cramping or sharp and lasts the first few days of the menstrual period. It may radiate to the back, thighs, or deep pelvis. Occasionally, nausea or vomiting occurs. Secondary dysmenorrhea may be due to endometriosis or cervical stenosis or, if associated with heavy menstrual flow, to fibroids, adenomyosis, or large endometrial polyps.

(Spec. 2:29 – 3:2; *see also* Harrison 1:8–11 (Harrison discloses that "[d]ysmenorrhea, which may be primary or secondary, is the occurrence of painful uterine cramps during menstruation. In secondary dysmenorrhea, there is a visible pelvic lesion to account for the pain, whereas only a biochemical imbalance is responsible for primary dysmenorrhea"); Bettendorf[5] 599:col. 1, ll. 8–13 ("In primary dysmenorrhea, pain is associated with the onset of menstrual flow with a typical duration of 2–3

[4] Edelstam, US 2003/0004213 A1 (publ. Jan. 2, 2003).
[5] Brittany Bettendorf et al., *Dysmenorrhea: Contemporary Perspectives*, 63 OBSTETRICAL & GYNECOLOGICAL SURVEY 597–603 (2008). We recognize Appellants' reliance on Bettendorf as an evidentiary document (*see* App. Br. 11).

days. In secondary dysmenorrhea, pain onset occurs 1–2 weeks before menstrual flow and persists beyond the cessation of bleeding").)

FF 2. Appellants disclose

> a pharmaceutical composition that includes an effective amount of a treating agent[, such as a local anesthetic], intended to reduce or relieve uterine dysrhythmia by normalizing propagation of the nerve impulses and/or nerve impulses or cell to cell communication (*i.e.*, faster, slower, or more consistent) causing the abnormal or undesireable [sic] contractions, together with a pharmaceutically acceptable bioadhesive carrier[, such as polycarbophil].

(Spec. 4:21–25; *see id.* at 6:19–22 (Appellants disclosure "relates to a method for treating or preventing pelvic pain that includes administering [a] composition vaginally," wherein "[s]uch administration demonstrates a therapeutic benefit for treating or preventing pelvic pain associated with uterine dysrhythmia"); *id.* at 15–16 (disclosing polycarbophil as bioadhesive, water-swellable, water-insoluble, cross-linked polycarboxylic acid polymer); App. Br. 22 (Claim 27: The method of claim 26, wherein the polymer comprises polycarbophil); *see* Harrison 2:15–24 (Harrison discloses "a method for treating a human female suffering from dysmenorrhea comprising contacting the vaginal epithelium of the female with a pharmaceutical agent[, such as a local anesthetic,] . . . in combination with a biocompatible excipient[, such as polycarbophil,] acceptable for application of the agent to the vaginal epithelium"]); Harrison 4:21–22 ("the biocompatible excipient can include . . . polycarbophil"); *see generally* Non-Final Act. 3–4.)

FF 3. Appellants define a "[l]ocal anesthetic[] . . . as a drug which may be used to provide local numbness or pain relief, by preventing the propagation of nerve impulses that relay or report the sensation of pain" (Spec. 4:31–33;

see generally Harrison 2:15–24 and 3:7–8; *see also*; *see generally* Non-Final Act. 3–4).

FF 4. Appellants disclose "[l]idocaine [as] a preferred anesthetic for use with [Appellants'] invention" (Spec. 5:1–2; *id.* at 7:15 ("a preferred local anesthetic for use with the present invention is lidocaine. Lidocaine is an antidysrhythmic agent"); *see* Harrison 12:16 ("[p]referred local anesthetics include Lidocaine"); *see also* Harrison 3:7–8; *see generally* Non-Final Act. 3–4).

FF 5. Appellants' composition, when administered, "diffuses through the vaginal mucosal into the target tissue," wherein "[r]elief from pain is provided by treatment or prevention of the cause or source of the pain, *e.g.*, increased or dysrhythmic contractility" (Spec. 6:32; id. at 34 – 7:1; *see id.* at 9:27–29 (Appellants disclose that their "invention . . . may be used to treat the underlying cause of the pain by delivering sufficient quantity of the treating agent to the affected tissue for an extended period of time"); *see also id.* at 6:6–9 ("The bioadhesive carrier includes a bioadhesive, water-swellable, water-insoluble, cross-linked polycarboxylic polymer. A preferred carrier, which may be in a gel formulation, contains a polycarbophil base designed to give controlled, extended release of the local anesthetic through the vaginal mucosa"); *see generally* Harrison 2:15–24; *see generally* Non-Final Act. 3–4).

FF 6. Appellants define the term "[p]revention" as "includ[ing] pre-treatment of pelvic pain, such as by administration of compounds in accordance with [Appellants'] invention, *preferably prior to onset of symptoms*, to a patient who is likely to experience pelvic pain, such as that due to uterine dysrhythmia," wherein, "[p]revention, or pre-treatment, *can*

be accomplished by administration of the compounds of the present invention about 2 to 3 days prior to the expected onset of symptoms" (Spec. 7:1–7 (emphasis added); *see* Harrison 24:12–16 (Harrison discloses the application of Harrison's composition "*several hours before* or just after onset of menstruation in order to treat or prevent dysmenorrhea. The treatment would continue for a few hours up to 2 to 3 days, as needed, to alleviate and prevent painful menstruation and symptoms") (emphasis added); *see generally* Non-Final Act. 3–4).

FF 7. Harrison discloses an "Ibuprofen Containing Gel for Intravaginal Application," wherein the "gel [is] comprised of the following ingredients: glycerin, mineral oil, *polycarbophil*, carbomer 934P, hydrogenated palm oil, glyceride, sodium hydroxide, sorbic acid, and purified water" (Harrison 30:15–19 (Example 7) (emphasis added)); *see also id.* at 32:1 and 10–13 ("Each of the drugs listed in this example [9, which includes *lidocaine (100 mg)*,] are substituted in Example 4, 5, 6 or 7, unless previously described, and repetition of the procedures there detailed affords other compositions according to [Harrison's] invention" (emphasis added)); *see generally* Non-Final Act. 3–4).

ANALYSIS

Examiner finds that Harrison anticipated Appellants' claimed invention (Non-Final Act. 3–5).

"Dysmenorrhea is associated with pain typically related to the menstrual cycle and can be primary or secondary" (FF 1). "[P]rimary dysmenorrhea . . . pain is cramping or sharp and lasts the first few days of the menstrual period" (*id.*). "In secondary dysmenorrhea, pain onset occurs 1–2 weeks before menstrual flow and persists beyond the cessation of

bleeding" (*id.*). Appellants' claim 26 is drawn to "[a] method of pre-treating or preventing pelvic pain associated with uterine dysrhythmia . . . , wherein the pelvic pain is also associated with secondary dysmenorrhea" (*see* App. Br. 22 (Appellants' claim 26)). We interpret the method of Appellants' claim 26 to require the pre-treatment or prevention of pelvic pain associated with uterine dysrhythmia, i.e., primary dysmenorrhea; wherein the pre-treatment or prevention of pelvic pain associated with uterine dysrhythmia, also treats pelvic pain associated with secondary dysmenorrhea (*cf.* Reply Br. 4 (Appellants' "claim terms make it clear that the claims address pelvic pain from dysrhythmia that is associated at least with secondary dysmenorrhea, regardless of whether or not any other cause also may be present, such as primary dysmenorrhea"); *see also id.* at 7).

Notwithstanding Appellants' contention to the contrary, Appellants' claim 26 requires the pre-treatment or prevention of pelvic pain associated with uterine dysrhythmia, wherein the pelvic pain is *also* associated with secondary dysmenorrhea (App. Br. 22 (Appellants' claim 26); *cf.* Reply Br. 7). There is no requirement in Appellants' claim 26 that the uterine dysrhythmia is associated with secondary dysmenorrhea. To the contrary, Appellants' claim 26 draws a clear distinction between pelvic pain associated with uterine dysrhythmia, i.e., primary dysrhythmia, and pelvic pain associated with secondary dysmenorrhea (*see* App. Br. 22 (Appellants' claim 26)). Thus, by pre-treating pelvic pain associated with dysrhythmia, i.e., primary dysmenorrhea, pelvic pain associated with secondary dysmenorrhea, which may occur prior to primary dysmenorrhea, is also treated.

Appellants and Harrison both disclose a method of pre-treating or preventing pelvic pain associated with uterine dysrhythmia, which comprises vaginally administering, to a patient in need thereof, a composition that includes a therapeutically effective amount of lidocaine and a bioadhesive, water-swellable, water-insoluble, cross-linked polycarboxylic acid polymer (i.e., polycarbophil), wherein the treatment is administered prior to anticipated onset of pelvic pain associated with uterine dysrhythmia so as to prevent pelvic pain associated with uterine dysrhythmia (FF 1–7; *cf.* App. Br. 22 (Appellants' claim 26)). Absent evidence to the contrary: (1) the administration of lidocaine according to Harrison's method will normalize abnormal uterine contractions (*see*, *e.g.*, FF 2–4; *cf.* App. Br. 22 (Appellants' claim 26); *see* Reply Br. 4) and Harrison's "a biocompatible excipient[, i.e., polycarbophil,]" will release lidocaine over an extended period of time after administration (*see*, *e.g.,* FF 2 and 5–7; *cf.* App. Br. 22 (Appellants' claim 26)). Further, absent evidence to the contrary, Harrison's method of pretreating or preventing pelvic pain associated with uterine dysrhythmia will necessarily treat pelvic pain associated with secondary dysmenorrhea (*see* FF 1–7; *cf.* App. Br. 22 (Appellants' claim 26); App. Br. 12 ("Examiner notes that 'Harrison does not distinguish between primary and secondary dysmenorrhea,' and . . . 'Harrison does not expressly teach pelvic pain associated with secondary dysmenorrhea'"); *see generally* App. Br. 12–13). Therefore, we are not persuaded by Appellants' contention that Harrison "effectively teach[es] away from [Appellants'] claim[26]" (Reply Br. 7). We also note that the Federal Circuit has determined that "[t]eaching away is irrelevant to anticipation." *Seachange Int'l, Inc., v. C-COR, Inc.*, 413 F.3d 1361, 1380 (Fed. Cir. 2005).

Harrison discloses the application of Harrison's composition "several hours before . . . onset of menstruation in order to treat or *prevent dysmenorrhea*" (FF 6) (emphasis added). Absent evidence to the contrary, Harrison's method, wherein Harrison's composition is administered prior to onset of menstruation, will necessarily pre-treat and/or prevent uterine dysthymia and, thereby, remove the cause of the pain (*see id.*; *see also* FF 1 ("primary dysmenorrhea[] pain is associated with the onset of menstrual flow"); *cf.* FF 6 (Appellants define the term "[p]revention" as "include[ing] pre-treatment of pelvic pain, such as by administration of compounds in accordance with [Appellants'] invention, preferably prior to onset of symptoms, to a patient who is likely to experience pelvic pain, such as that due to uterine dysrhythmia"); *see* Reply Br. 5–6).

Therefore, we are not persuaded by Appellants' contentions that "Harrison does not seek, teach, disclose, or otherwise acknowledge treatment of dysmenorrhea other than by successfully treating the resulting pain and discomfort" or that "[t]here is absolutely no recognition or teaching that a treatment could actually remove the cause of the pain, rather than just treat the resulting pain" (App. Br. 10). For the foregoing reasons, we are not persuaded by Appellants' contention that the timing of Harrison's administration, i.e., prior to the onset of menstruation, "focuses on treating the pain and discomfort of primary dysmenorrhea, and not pre-treating by normalizing the underlying dysrhythmic cause" (App. Br. 10; *cf.* FF 6). In this regard, Appellants fail to provide persuasive evidence or argument to support a finding that the vaginal administration of Harrisons' composition, which comprises lidocaine and polycarbophil prior to the onset of menstruation (i.e., primary dysmenorrhea), will result in a different result

than the vaginal administration of Appellants' composition, which comprises lidocaine and polycarbophil, prior to the anticipated onset of pelvic pain associated with uterine dysrhythmia (i.e., primary dysmenorrhea) (*see* FF 2–7; *cf.* App. Br. 22 (Appellants' claim 26); Reply Br. 4–6).

"Attorney's argument in a brief cannot take the place of evidence." *In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974)). Therefore, we are not persuaded by Appellants' unsupported contentions regarding the timing of menstruation or assertion that Harrison's disclosure of "prevent[ing] painful menstruation and symptoms" is inaccurate (App. Br. 10–12; *cf.* FF 6). Appellants' claim 26 does *not* require administration of Appellants' composition at any specific time prior to the anticipated onset of pelvic pain associated with uterine dysrhythmia (*see* App. Br. 22 (Appellants' claim 26); *cf.* Reply Br. 4 ("Harrison does not administer lidocaine early enough to 'pretreat or prevent' symptoms -- even for primary dysmenorrhea")). Therefore, we are not persuaded by Appellants' contention that "preventing and pre-treating the discomfort by pre-treating the dysrhythmia itself – as contemplated by the instant invention -- requires administration as much as about 2-3 days before the next-anticipated menstruation for primary dysmenorrhea, and even much earlier for secondary dysmenorrhea," which is not commensurate in scope with Appellants' claimed invention (App. Br. 11; *cf.* FF 6 (Appellants' "[p]revention, or pre-treatment, can be accomplished by administration of the compounds of the present invention about 2 to 3 days prior to the expected onset of symptoms")). "[W]hile it is true that claims are to be interpreted in light of the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims." *Sjolund v. Musland*, 847 F.2d

1573, 1581 (Fed. Cir. 1988). Moreover, "during patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed." *In re Zletz*, 893 F.2d 319, 322 (Fed. Cir. 1989).

For the foregoing reasons, we are not persuaded by Appellants' contention that Harrison's method will not also treat pelvic pain associated with secondary dysmenorrhea as required by Appellants' claim 26 (*see* App. Br. 12; *see generally* Reply Br. 7–8).

CONCLUSION OF LAW

The preponderance of evidence on this record supports Examiner's finding that Harrison teaches Appellants' claimed invention. The rejection of claim 26 under 35 U.S.C. § 102(b) as being anticipated by Harrison is affirmed. Claims 3–7, 10, 11, 27, 45, and 46 are not separately argued and fall with claim 26.

Obviousness:

ISSUE

Does the preponderance of evidence relied upon by Examiner support a conclusion of obviousness?

FACTUAL FINDINGS (FF)

FF 8. Examiner finds that Harrison does not disclose the administration of Harrison's "composition more than 3 days before onset of any symptom(s)" and relies on Edelstam to make up for this deficiency in Harrison (Non-Final Act. 6–7).

ANALYSIS

Based on the combination of Harrison and Edelstam, Examiner concludes that, at the time Appellants' invention was made, it would have been prima facie obvious "to combine the teachings of Harrison and Edelstam because both references teach compositions comprising lidocaine that are useful in treating pain associated with dysmenorrhea by vaginally administ[ering]" Harrison's composition according to Harrison's method (Non-Final Act. 7; *see* FF 1–7).

Appellants do not separately argue the claims on Appeal, therefore, Appellants' claim 26 is representative. In this regard, we recognize Examiner's assertion that "Harrison does not expressly teach pelvic pain associated with secondary dysmenorrhea" (Non-Final Act. 6). For the reasons discussed above, however, we find that Harrison's method inherently teaches the treatment of pelvic pain associated with secondary dysmenorrhea. Therefore, having found Appellants' claim 26 anticipated by Harrison, we find Appellants' claim 26 obvious over Harrison.[6] *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983) ("anticipation is the epitome of obviousness").

Therefore, for the reasons set forth above, we are not persuaded by Appellants' contentions that Appellants' claim 26 is non-obvious in view of Harrison (*see* App. Br. 14–20; Reply Br. 8–13).

[6] The Board may rely upon less than all the references cited by the Examiner. *See In re May*, 574 F.2d 1082, 1090 (CCPA 1978); *In re Kronig*, 539 F.2d 1300, 1304 (CCPA 1976).

CONCLUSION OF LAW

The preponderance of evidence relied upon by Examiner supports a conclusion of obviousness. The rejection of claim 26 under 35 U.S.C. § 103(a) as unpatentable over the combination of Harrison and Edelstam is affirmed. Claims 3–7, 10, 11, 27, 45, and 46 are not separately argued and fall with claim 26.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED